US ERA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Propylene Oxide (PPO) RED Addendum June 2009

Richard Keigwin, Jr.

Director

Special Review and Reregistration Division

CORRECTION TO NOVEMBER 14, 2008 Propylene Oxide (PPO) RED ADDENDUM

The Environmental Protection Agency (EPA or the Agency) is publishing a correction to the November 14, 2008 Propylene Oxide (PPO) RED Addendum. The initial PPO RED Addendum was issued on September 25, 2008 because of an error in the PERFUM model in the July 2006 RED. The PPO RED Addendum was revised on November 14, 2008 to insert a missing word. These documents are posted on www.regulations.gov, documents EPA-HQ-OPP-2005-0253-0070 and EPA-HQ-OPP-2005-0253-0075 respectively.

Since the November 14, 2008 version, the registrant indicated that the following language, "During the aeration period there must be a minimum of 20 air changes per hour," is not feasible for vacuum fumigations equipped with emission control technology because of the efficacy of the pumps and the time needed to bring the chamber to vacuum in an hour. The registrant also asked the Agency to consider an additional mitigation scenario (higher stack and fewer air changes) for fumigators without emission control technology.

For vacuum chambers with emission control technology that reduces PPO emissions by at least 95%, the Agency has determined that 20 air changes an hour is not necessary to make a safety finding because standard ventilation procedures are adequate. The label language will be revised as appropriate.

For vacuum chambers without emission control technology, the registrant submitted PERFUM modeling runs (MRID 47692001) with higher stack heights and fewer air changes per hour. The Agency has reviewed these runs and determined that this scenario still allows the Agency to make a safety finding and additional language will be added to the label. For a detailed review please see the following document in the PPO docket EPA-HQ-OPP-2005-0253, "Propylene Oxide: Review of Submitted PERFUM Results (RED Case 2560)," (Crowley, 2009).

As a result of this review, the Agency is revising the PPO RED where appropriate. These revisions are listed below and the corresponding amended label language is included in Table 1.

For Fumigation in Vacuum-Sealed Pressurized Chambers

- For all applications of PPO > 75 lbs ai/1,000 ft3 (1.2 oz/ft3) and ≤ 150 lbs ai/1,000 ft3 (2.4 oz/ft3), the chamber must be equipped with equipment specifically designed to reduce PPO emissions by at least 95 percent.
- For chambers ≤ 5,000 ft3 with PPO application rates of 75 lbs ai/1,000 ft3 (1.2 oz/ft3) and below:
 - o a chamber must have a release height of at least 27 feet and during the aeration period there must be a minimum flow rate through the stack equivalent to at least 20 air changes per hour, OR
 - o a chamber must have a release height of at least 40 ft and a minimum flow through the stack equivalent to at least 4 air changes per hour, OR

- o the chamber must be equipped with equipment specifically designed to reduce PPO emissions by at least 95 percent.
- For chambers > 5,000 ft3 and $\le 10,000$ ft3 with application rates of PPO 75 lbs ai/1,000 ft3 (1.2 oz/ft3) and below:
 - o a chamber must have a release height of at least 40 feet and during the aeration period there must be a minimum flow rate through the stack equivalent to at least 20 air changes per hour, OR
 - o the chamber must be equipped with equipment specifically designed to reduce PPO emissions by at least 95 percent.

Table 1. Revised summary of required labeling changes for PPO products

Manufacturing-Use Products			
Description	Amended Labeling Language	Placement on Label	
For all Manufacturing-Use Products	"Propylene oxide only can be formulated into end-use products containing directions for use that include acceptable air concentration levels of 2 ppm as an 8-hour time weighted average and other measures for ensuring that workers and other persons are not exposed to concentrations of propylene oxide that exceed this level unless appropriate respiratory protection is used."	Directions for Use	
	"Propylene oxide cannot be formulated into end-use products labeled for use on edible gums or birdseed. End-use product labels must be revised to delete all references to and use directions for edible gums or birdseed."		
	"Propylene oxide only can be formulated into end-use products that are classified as and identified as Restricted Use."		
One of these statements may be added to a label to allow reformulation of the product for a specific use or usepattern or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use	
Environmental Hazards Statements Required by the RED and Agency Label Policies	"ENVIRONMENTAL HAZARDS This pesticide is toxic to birds and mammals. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements	
	End-Use Products Intended for Occupational Use		
Description	Amended Labeling Language	Placement on Label	
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE DUE TO INHALATION TOXICITY For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."	Top of Front Panel	
Identify as a fumigant all propylene oxide end-	Prominently identify the end-use product as a "Fumigant"	Insert the word "fumigant" as part of the product name or close to the product	

use products		name, either as part of the product-type identification or as a separate word or sentence
Add precautionary language in Spanish on propylene oxide end-use products	Add the following Spanish signal word and statement: "PELIGRO Si Usted no entiende la etiqueta, busque a alquien para que se la explique a Usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)"	On front panel of the label near the signal word DANGER.
Add acceptable air concentration language to propylene oxide enduse products	"AIR CONCENTRATION LEVEL The acceptable air concentration level for persons exposed to propylene oxide is 2 ppm (8 mg/m³) as a time-weighted average."	In the Hazards to Humans and Domestic Animals section of the labeling immediately following the precautionary statements.
PPE Requirements Established by the RED for propylene oxide end-use products ^a	"PERSONAL PROTECTIVE EQUIPMENT Some materials that are chemical-resistant to this product are (registrant inserts correct chemical-resistant material). If you want more options, follow the instructions for category [registrant inserts A, B, C, D, E, F, G, or H] on an EPA chemical-resistance category selection chart. All handlers opening propylene oxide drums or tanks, cleaning up leaks or spills, or who otherwise may potentially contact liquid propylene oxide, must wear: > long-sleeved shirt and long pants, > chemical-resistant gloves, > chemical-resistant footwear plus socks, > chemical-resistant apron. > face-sealing goggles, and > full-face shield, unless a respirator that covers the entire face is worn. Respirator Requirements: Once propylene oxide has been introduced into an enclosure, the certified applicator supervising the fumigation must make sure that all persons in the exposure area (the treatment area and the buffer zone, if applicable) have appropriate respiratory protection or are removed from the exposure area. Air Concentrations 10 PPM or Greater from a Direct-read Device or Air Concentrations Greater than 2 ppm as an 8-Hour Time Weighted Average: If propylene oxide air concentration level is measured to be 10 ppm or greater at anytime when measured using a direct read device or if propylene air concentration exceeds 2 ppm as an 8-hour time weighted average, each person in the exposure area must wear either; • a supplied-air respirator (MSHA/NIOSH approval number TC-19C), or • a self-contained breathing apparatus (SCBA) (MSHA/NIOSH	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

	approval number profix TC 12E\	· · · · · · · · · · · · · · · · · · ·
	 approval number prefix TC-13F). any NIOSH-approved air purifying respirator (APR) outfitted with an organic vapor canister/cartridge and an end-of-service-life indicator (ESLI) certified by NIOSH for the contaminant (APR is not approved for IDLH situations); or any NIOSH-approved air purifying respirator (APR) outfitted with an organic vapor canister/cartridge for which, if there is no ESLI certified by NIOSH for the contaminant, the employer implements a change schedule for canisters and cartridges that is based on documented objective information or data that will ensure that canisters and cartridges are changed before the end of their service life (APR is not approved for IDLH situations). Air Concentrations lower than 10 ppm from a Direct-read Device, and Air Concentrations at or below 2 PPM as an 8-hour Time Weighted Average: No respirator is required if the air concentration level of propylene oxide in the exposure area is measured to be lower than 10 ppm using a direct-read device and the air concentration is at or below 2 ppm as an 8-hour time weighted average." 	
User Safety Requirements for all propylene oxide end- use products	"WORK SAFETY REQUIREMENTS Respirator Requirements: When a respirator is required for use with this product, the certified applicator supervising the fumigation must make sure that:	Precautionary Statements: Hazards to Humans and Domestic Animals immediately
	a) Respirators must be fit tested and fit checked using a program that conforms with OSHA's requirements (described in 29 CFR Part 1910.134); b) Respirator users must be trained using a program that conforms with OSHA's requirements (described in 29 CFR Part 1910.134); c) Respirator users must be examined by a qualified medical practitioner to ensure the physical ability to safely wear the style of respirator to be worn; d) Respirators must be maintained according to a program that conforms with OSHA's requirements (described in 29 CFR Part 1910.134).	following Personal Protective Equipment Requirements
	If liquid fumigant splashes or spills on clothing, remove them at once, and place them outdoors in an isolated place to aerate, because fumes will be an intolerable source of irritation.	z.
	Immediately after application remove personal protective equipment. Do not reuse the personal protective equipment until cleaned. Keep and wash the work clothing and personal protective equipment separately from other laundry.	
	Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them.	
	Follow manufacturer's instructions for cleaning/maintaining personal protective equipment."	
User Safety Recommendations	"User Safety Recommendations	Precautionary Statements under:
	Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.	Hazards to Humans and Domestic

	Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Animals immediately following User Safety Requirements (Must be placed in a box.)
Application Restrictions	"The maximum size enclosure that is allowed to be fumigated is 10,000 ft ³ ."	In the Directions for Use section.
Restrictions for Vacuum-Sealed Pressurized Chambers	"Fumigation in Vacuum-Sealed Pressurized Chambers For all applications of PPO > 75 lbs ai/1,000 ft3 (1.2 oz/ft3) and ≤ 150 lbs ai/1,000 ft3 (2.4 oz/ft3), the chamber must be equipped with equipment specifically designed to reduce PPO emissions by at least 95 percent. For chambers ≤ 5,000 ft3 with PPO application rates of 75 lbs ai/1,000 ft3 (1.2 oz/ft3) and below:	In the Directions for Use under "Fumigation in Vacuum-Sealed Pressurized Chambers"
	 a chamber must have a release height of at least 27 feet and during the aeration period there must be a minimum flow rate through the stack equivalent to at least 20 air changes per hour, OR a chamber must have a release height of at least 40 ft and a minimum flow through the stack equivalent to at least 4 air changes per hour, OR the chamber must be equipped with equipment specifically designed to reduce PPO emissions by at least 95 percent. For chambers > 5,000 ft3 and ≤ 10,000 ft3 with application rates of PPO 75 lbs ai/1,000 ft3 (1.2 oz/ft3) and below: a chamber must have a release height of at least 40 feet and during the aeration period there must be a minimum flow rate through the stack equivalent to at least 20 air changes per hour, OR the chamber must be equipped with equipment specifically designed to reduce PPO emissions by at least 95 percent." 	·
Restrictions for Fumigation Not Contained within a Vacuum-Sealed Pressurized Chamber	"Fumigation in a Non Vacuum-Sealed Pressurized Chamber (atmospheric chambers or structures, railcars, trailers, air/sea transport containers, tents, and tarps) For any fumigation that takes place in a non vacuum-sealed pressurized chamber the appropriate buffer zone (see below) must be established around the treated enclosure from the time propylene oxide is introduced into the enclosure and must remain in effect until the air concentration of propylene oxide being exhausted from the treated enclosure is measured to be 10 ppm or less. • For chambers that are passively aerated the buffer zones in Table 1 are required during treatment and aeration. Table 1. Enclosure Size Buffer Zone ≤ 1,000 ft³ 10 feet	In the Directions for Use under the heading: Fumigation Not Contained Within a Vacuum- Sealed Pressurized Chamber" immediately following "Fumigation in Vacuum-Sealed Pressurized Chambers"

		¥i		
	$> 1,000 \text{ ft}^3 \text{ and } \le 2,000$	50 feet		
		115 feet		
		200 feet		
	During aeration if the chamb			
	changes per hour with a 10 fe			
Ta.	the product, chamber, or stru must be established around the			
	Fumigation taking place in a non vacuum-sealed pressurized chamber is limited to a maximum concentration of 0.0448 ounces of propylene oxide per cubic foot of fumigation enclosure.			
	Buffer Zone Entry Restrictions Entry by the certified applicator super under his/her direct supervision, is per		•	
ű	either: the appropriate respirator is worn (s	(%)	· •	
	this labeling); OR			
	the air concentration level for propy an 8-hour time weighted average.	viene oxide is at or being	ow 2 ppm for	
	The certified applicator supervising the fumigation must ensure that any			-
	person, except the certified applicator or persons under his/her direct supervision, is kept outside the buffer zone surrounding the treated			
	enclosure from the time propylene oxide is introduced into the enclosure			
	until the air concentration of propylen treated enclosure is measured to be 10		a from the	= .
Onsite Notification	"PLACARDING OF FUMIGATED	ENCLOSURES		In the Directions for
for all propylene				Use under the
oxide end-use products	The certified applicator supervising th direct supervision) must placard all en with signs bearing:			heading "PLACARDING OF FUMIGATED
	skull and crossbones symbol "DANGER/PELIGRO,"			ENCLOSURES"
	"Area under fumigation, DO NOT I			
	"Propylene Oxide Fumigant in use," the date and time of fumigation, and			
	name, address, and telephone number supervising the fumigation."	er of the certified appli	icator	
	"The certified applicator supervising to			
	person, except the certified applicator supervision who are wearing appropria the treated enclosure until the signs are removed when aeration has occurred a	ate respiratory protecti e removed. Such signs and when the air conce	on, enters into s must only be ntration level	e e
	of propylene oxide is monitored as des monitoring indicates that workers can Signs must remain legible during entir	enter without respirate		
	The warning signs at entrances to fum removed by the certified applicator supplicator supplications are supplied to the certified applications of the certified applications are supplied to the certified applications of the certified applications are supplied to the certified applied to the certified to the cer			

	under his/her direct supervision.	
	Vehicles must be placarded with applicable U.S. Department of Transportation warning signs."	
Environmental Hazards Statements	"ENVIRONMENTAL HAZARDS This pesticide is toxic to birds and mammals. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plants authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements under Environmental Hazards
Storage and Disposal language of for all propylene oxide end- use products	"Persons moving, handling, or opening containers must wear the personal protective equipment (including prescribed respirators when necessary) specified in the Human Hazards section of this labeling. Store containers in a well-ventilated area."	Storage and Disposal section of the label
Spill and Leak Procedures of for propylene oxide end- use products	Evacuate everyone from the immediate area of the spill or leak. For entry into affected area to correct problem, wear the personal protective equipment (including prescribed respirators) specified in the Hazards to Humans section of this labeling. Move leaking or damaged containers outdoors or to an isolated location. Observe strict safety precautions. Work upwind, if possible. Allow spilled fumigant to evaporate. Only correctly trained and PPE-equipped handlers are permitted to perform such cleanup. Do not permit entry into the spill or leak area by any other person until the air concentration level of propylene oxide is measured to be at or below 2 ppm as an 8-hour time weighted average. Contaminated soil, water, and other cleanup debris is a toxic hazardous waste. Report spill to the National Response Center (800-424-8802) if the reportable quantity of 1000 lbs. is exceeded."	In the labeling section titled "Storage and Disposal" or by themselves under the heading "Spill and Leak Procedures"
General Application Restrictions	"DIRECTIONS FOR USE It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.	Place in the Direction for Use directly below the heading "Directions for Use"
	Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation."	

^a PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.